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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/554,451	05/15/2000	JONATHAN P MURPHY	PM-268066	2087

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EXAMINER

SISSON, BRADLEY L

ART UNIT PAPER NUMBER

1655

DATE MAILED: 01/29/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/554,451

Applicant(s)

MURPHY ET AL.

Examiner

Bradley L. Sisson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 November 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 and 27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 and 27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Claim Objections

1. Claims 3 and 5 are objected to because of the following informalities: In claim 3 there is no semicolon immediately prior to the use of the term “or.” The use of --and-- or --or-- would appear to be in order in claim 5, immediately following “semen;”. Appropriate correction is required.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-12 and 27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 defines the method as being one “wherein the exogenously administered polypeptide is tagged with a greater or lesser amount of fluorescent activity.” Said claim 1 also further limits the source of said “fluorescent activity” as being a “tag.” The “endogenous polypeptide” is also defined in said claim 1 as being “the untagged molecule.” With the endogenous polypeptide not being tagged, it would by default be incapable of exhibiting any fluorescence, as the claim requires that the selected fluorescent wavelength is due only to the presence of the tag. Accordingly, it is anything but clear how one would be able to perform the requisite “determination” when a) the exogenous polypeptide has less fluorescent label than the

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endogenous polypeptide; and b) the tagged exogenous polypeptide exhibits less fluorescent signal than that of the endogenous polypeptide. As presently worded, the scenarios of a) and b) are seemingly impossible to achieve.

4. Claim 27 recites the limitation "the substitution" in line 2. There is insufficient antecedent basis for this limitation in the claim.

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1-12 and 27 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. As presently worded, the method of claims 1-12 and 27 encompass, and outright limit the claim to multiple scenarios that are seemingly incapable of being achieved. As set forth above, the claim directs one of skill in the art to make a determination when the fluorescent signal of the tagged, exogenously administered polypeptide is less than that of the untagged, endogenous polypeptide. With the fluorescent signal only arising from the presence of a "tag" or some fluorescent moiety which is limited to being present on only the exogenously administered polypeptide, it is impossible therefore for the endogenous polypeptide to produce any fluorescent signal, much less produce a signal that has an intensity greater than that of the tagged, exogenously administered polypeptide.

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7. The specification does not enable the claimed method where the method is based upon the use of tyrosine or tryptophan. As presently worded, the method makes no allowances for differences in fluorescent signal generated from the presence of these amino acid residues where the polypeptide acts as a receptor and in fact undergoes binding to its ligand, e.g., tryptophan substitutions in calmodulin that is allowed to bind to Ca^{2+} ions. As set forth in the article by Kilhoffer et al., they observed changes in intensity of fluorescence as well as changes in fluorescence polarization degree when the substituted calmodulin bound to Ca^{2+} ions. Such changes in intensity would directly impact on the results obtained from measuring the intensity of fluorescent signal (applicant's "fluorescence activity"). The specification is essentially silent as to how this art-recognized difficulty is to be overcome. With the tagged sample and the untagged sample both having been administered to the patient, it stands to reason that the polypeptide, which can be virtually any polypeptide, including calmodulin, would be exposed to ligands or receptors, depending upon the nature of the polypeptide at issue.

Conclusion

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

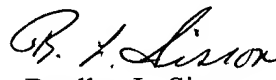
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will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradley L. Sisson whose telephone number is (703) 308-3978. The examiner can normally be reached on 6:30 a.m. to 5 p.m., Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.


Bradley L. Sisson
Primary Examiner
Art Unit 1655

bls
January 22, 2002